EXHIBIT 13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Michael L. Green, et al.
Reexam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Jeanne Marie Clark
Art Unit	:	3993
Conf. No.	:	1162

PETITION UNDER 37 C.F.R. § 1.182

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to M.P.E.P. § 2287.01, Patentee respectfully submits this Petition under 37 C.F.R. § 1.182 to have the Examiner consider the accompanying Information Disclosure Statement in the above-referenced reexamination proceeding. This Information Disclosure Statement was previously filed on April 12, 2011, a date which was within two-months from the date of the Order Granting the Request for Ex Parte Reexamination, which issued on February 16, 2011.

A Notice of Intent to Issue Ex Parte Reexamination Certificate was issued by the Examiner on March 28, 2011. In a telephone conference with the Examiner, the undersigned was informed that the Information Disclosure Statement filed on April 12, 2011 would not be considered without a granted petition under 35 C.F.R. § 1.182. Accordingly, the Patentee is hereby re-submitting the Information Disclosure Statement with this petition.

Patentee respectfully submits that the initial Information Disclosure Statement filed on April 12, 2011 was timely because it was filed "within two (2) months of the date of the order for

reexamination" pursuant to 37 C.F.R. § 1.555(a). Thus, Patentee was in full compliance with the Rules regarding the timing for filing an Information Disclosure Statement in a reexamination proceeding. Accordingly, Patentee respectfully submits that the present petition should be granted. To hold otherwise would render Rule 1.555(a) ineffective and meaningless. Patentee should not be punished for relying in good faith on the plain language of the Code of Federal Regulations.

Patentee respectfully submits that the information submitted with the accompanying Information Disclosure Statement does not render any claim unpatentable. Nonetheless, Patentee submits that consideration of this information by the Examiner is appropriate. The M.P.E.P. advises that applicants should submit information "even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office." M.P.E.P. § 2001.05. Accordingly, Patentee believes it appropriate for the Examiner to make an independent determination regarding the materiality of the submitted information.

This Petition is being submitted with the fee as set forth in 37 C.F.R. 1.17(f) for a petition under 37 C.F.R. 1.182. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 28, 2011

By: Ryan Melnick

Ryan E. Melnick
Registration No. 58,621
Attorney of Record
Customer No. 20,995
(858) 836-9000

11136884
042711

INFORMATION DISCLOSURE STATEMENT

Applicant	:	Michael L. Green, et al.
Reexam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Clark, Jeanne Marie
Art Unit	:	3993
Conf. No.	:	1162

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified re-examination is a PTO/SB/08 Equivalent listing 3 references, of which 3 are enclosed/submitted.

This Information Disclosure Statement is accompanied by a Petition under 37 C.F.R. § 1.182. This Information Disclosure Statement is identical to the one filed on April 12, 2011, which was filed "within two (2) months of the date of the order for reexamination" pursuant to 37 C.F.R. § 1.555. No fee is required. Nonetheless, if the Patent Office determines that a fee is required, the Commissioner is authorized to charge any such required fees to Deposit Account No. 11-1410.

Enclosed and listed on the PTO/SB/08 is a Statement of Tate Scott. If the Examiner requires any further information regarding the contents this statement, she is invited to contact the undersigned or request such information pursuant to 37 C.F.R. § 1.105.

Application No.: **90/011430**
Filing Date: **January 11, 2011**

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 28, 2011

By: Ryan Melnick

Ryan E. Melnick
Registration No. 58,621
Attorney of Record
Customer No. 20,995
(858) 836-9000

11146280
042811

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/011430
	Filing Date	January 11, 2011
	First Named Inventor	Michael L. Green, et al.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Clark, Jeanne Marie
SHEET 1 OF 1	Attorney Docket No.	KFX.003RX

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	1	Mazzocca et al., "Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," *The American Journal of Sports Medicine*, 33:1861 (2005).	
	2	Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.	
	3	Statement of Tate Scott, dated April 12, 2011.	

11016104/adk/040611

Examiner Signature	Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair

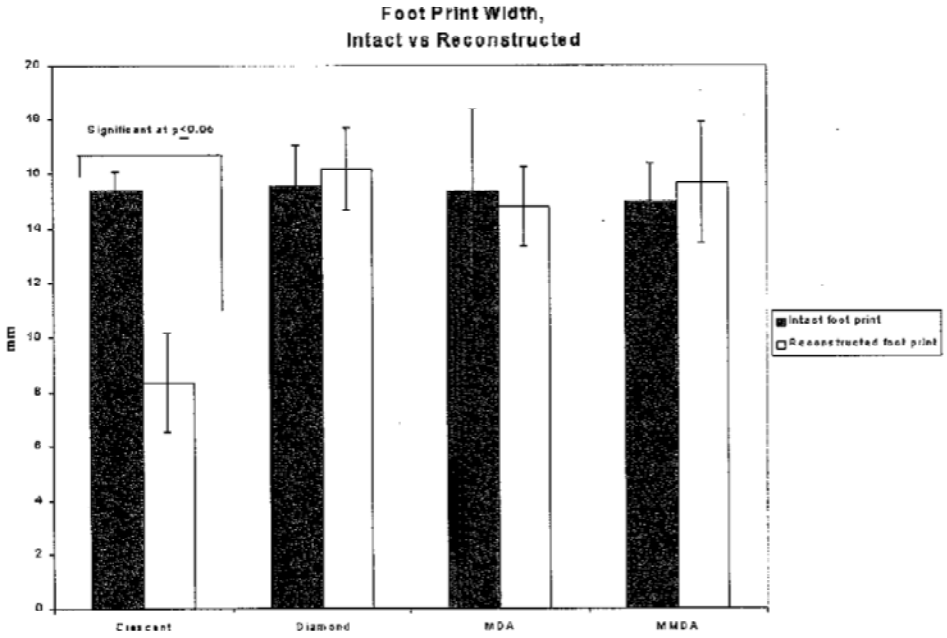
Authors:
Augustus D. Mazzocca MD, Peter J. Millett MD, Stephen A. Santangelo, Robert A. Arciero MD, (Farmington, CT; Boston, MA)

Objective:
Maximizing mechanical and biologic healing potential while minimizing surgical morbidity is the goal of arthroscopic rotator cuff repair (ARCR). The purpose of this study was to evaluate four ARCR techniques. The hypothesis is that a double row anchor repair is superior to a single row repair.

Methods:
Twenty (10 male; 10 female) fresh frozen cadaver shoulders (Mean age 76.3+13.4) were randomly assigned to four repair techniques (Crescent(C), Diamond (D), Mattress Double Anchor (MDA), and Modified Mattress Double Anchor (MMDA)). Angle of pull(135 degrees), anchor type, Bone mineral density(BMD), anchor distribution, angle of anchor insertion, arthroscopic technique, suture type and suture size were all controlled. The number of arthroscopic instrument passes through the tendon was recorded. Tendon length and width was quantified pre and post repair. Displacement of the repaired tendon to bone with repetitive submaximal cyclic load (3000 cycles at 1 Hz with 100 N) was quantified. Load to failure was assessed at 31mm/min after cyclic loading. A gap formation greater than 4mm and a load to failure less than 250N was considered a biomechanical failure.

Results:
There were no differences between the groups for age, sex, or bone mineral density. There was a significant $P<0.05$ greater supraspinatus footprint width and less suture passes through tendon with the double row than single row technique. There was no evidence for large effect size differences in repetitive submaximal cyclic loading or load to failure (Cohens distribution =0.8) All groups demonstrated significantly ($p<0.05$) less displacement when compared to a standard 4mm gap formation. All groups demonstrated significantly greater load to failure than the standard 250 N. 2/20 samples demonstrated anchor pull out and 18/20 failed with suture pulling through the tendon.

(cont.)
Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair



Conclusions:
All groups demonstrated superior biomechanical properties when compared to previously reported population limits. There was no difference in cyclic load or load to failure between any of the groups. The double row anchor repair had less passes through the tissue, equal mechanical properties, and a consistently larger footprint which may aide in biologic healing.

The American Journal of Sports Medicine

http://ajs.sagepub.com/

Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair

Augustus D. Mazzocca, Peter J. Millett, Carlos A. Guanche, Stephen A. Santangelo and Robert A. Arciero

Am J Sports Med 2005 33: 1861
DOI: 10.1177/0363546505279575

The online version of this article can be found at:
http://ajs.sagepub.com/content/33/12/1861

Published by:
SAGE
http://www.sagepublications.com

On behalf of:
AOSSM
American Orthopaedic Society for Sports Medicine

Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair

Augustus D. Mazzocca,*† MD, Peter J. Millett,‡ MD, Carlos A. Guanche,§ MD, Stephen A. Santangelo,† and Robert A. Arciero,† MD

From the †Department of Orthopaedic Surgery, University of Connecticut Health Center, Farmington, Connecticut, ‡Harvard Shoulder Service, Brigham and Women's Hospital, Boston, Massachusetts, and the §Southern California Orthopaedic Institute, Van Nuys, California

Background: Recurrent defects after open and arthroscopic rotator cuff repair are common. Double-row repair techniques may improve initial fixation and quality of rotator cuff repair.

Purpose: To evaluate the load to failure, cyclic displacement, and anatomical footprint of 4 arthroscopic rotator cuff repair techniques.

Hypothesis: Double-row suture anchor repair would have superior structural properties and would create a larger footprint compared to single-row repair.

Study Design: Controlled laboratory study.

Methods: Twenty fresh-frozen cadaveric shoulders were randomly assigned to 4 arthroscopic repair techniques. The repair was performed as either a single-row technique or 1 of 3 double-row techniques: diamond, mattress double anchor, or modified mattress double anchor. Angle of loading, anchor type, bone mineral density, anchor distribution, angle of anchor insertion, arthroscopic technique, and suture type and size were all controlled. Footprint length and width were quantified before and after repair. Displacement with cyclic loading and load to failure were determined.

Results: There were no differences in load to failure and displacement with cyclic loading between the single-row repair and each double-row repair. All repair groups demonstrated load to failure greater than 250 N. A significantly greater supraspinatus footprint width was seen with double-row techniques compared to single-row repair.

Conclusions: The single-row repair technique was similar to the double-row techniques in load to failure, cyclic displacement, and gap formation. The double-row anchor repairs consistently restored a larger footprint than did the single-row method.

Clinical Relevance: The arthroscopic techniques studied have strong structural properties that approached the reported performance of open repair techniques. Double-row techniques provide a larger footprint width; although not addressed by this study, such a factor may improve the biological quality of repair.

Keywords: rotator cuff; shoulder; biomechanics; arthroscopy

In the past decade, arthroscopic repair has become a well-established surgical technique for the treatment of complete rotator cuff tears. Clinical results have been extremely satisfactory in managing small, medium, large, and massive rotator cuff tears.[2,6,11,14,18,19,21,22] Long-term follow-up evaluations have revealed that excellent clinical outcomes can be maintained.[11,14,21,22] A recent retrospective study comparing arthroscopic to mini-open rotator cuff repairs demonstrated comparable outcome results, with a decreased incidence of fibrous ankylosis and a trend for improved motion with the arthroscopic technique.[18]

Despite these apparent favorable reports, recurrent tears after open and arthroscopic rotator cuff repair remains one of the most common complications. A review of studies examining rotator cuff integrity after open surgery has demonstrated that the retear rate can be more than 50%.[7,10] Interestingly, recurrent defects after open rotator cuff repair have not correlated with clinical outcome. However, shoulders with intact repairs do appear to have substantially better functional results than those with recurrent tears.[7,8,10,16] A study on repair integrity

*Address correspondence to Augustus D. Mazzocca, MD, Department of Orthopaedic Surgery, University of Connecticut, 10 Talcott Notch Road, Farmington, CT 06034 (e-mail: admazzocca@yahoo.com).

One or more of the authors has declared a potential conflict of interest as specified in the AJSM Conflict of Interest statement.

The American Journal of Sports Medicine, Vol. 33, No. 12
DOI: 10.1177/0363546505279575

after arthroscopic rotator cuff repair was recently reported by Galatz et al.[5] They reported an alarming rate of 89% for recurrent defects. More important, they reported a significant deterioration in clinical outcome between the 12- and 24-month periods after surgery.

Criticisms of the arthroscopic technique have included the inferior mechanical strength of suture anchor repair, especially when a simple suture technique is used.[9,12,17] In addition, there are reports that the suture anchor technique restores only 67% of the original footprint of the rotator cuff compared with the transosseous simple suture repair, which restored 85% of the surface area.[1] Yet it has been suggested that a double-row arthroscopic rotator cuff repair could reestablish the normal footprint of the rotator cuff, improve mechanical integrity, and improve healing with improved clinical outcomes. In a cadaveric study, Waltrip et al[20] demonstrated markedly improved mechanical performance with cyclic loading using a double-row fixation technique performed in an open fashion.

To our knowledge, there has been no biomechanical study evaluating various arthroscopic single-row and double-row rotator cuff repair techniques. The purpose of this study was to evaluate single-row fixation versus 3 different double-row repairs using a simulated arthroscopic technique for each repair. The repair footprint, response to cyclic loading, and ultimate load to failure were measured for comparison of the 4 methods. Our hypothesis was that double-row anchor repair would be superior to single-row repair with regard to reestablishing the supraspinatus footprint, response to cyclic loading, and ultimate failure strength.

MATERIALS AND METHODS

Twenty fresh-frozen cadaveric shoulders were used in this study. The mean age of these specimens was 76.3 years, with a range from 62 to 90 years. After these specimens were thawed, bone density was measured (Lunar DXE, Madison, Wis) at the greater tuberosity in a consistent manner at a 1 × 1-cm area at the site of anticipated anchor placement. The deltoid muscle was removed from the acromion, providing complete access to the coracoacromial arch, rotator cuff, and glenohumeral joint. The supraspinatus tendon and muscle were elevated from the supraspinatus fossa and reflected laterally to expose the articular aspect of the anatomical footprint of the supraspinatus insertion. Laterally, the bursal surface fibers of the supraspinatus insertion on the greater tuberosity were exposed. All footprint measurements were performed by the same examiner (S.A.S.); the footprint was measured using a digital caliper (Absolute Digimatic, Mitutoyo Corp, Kawasaki, Japan), with width and length dimensions calculated to the nearest 0.01 mm. While the supraspinatus muscle was held in tension in a superior direction, the width of the footprint at its greatest dimension was measured by placing 1 limb of the digital caliper precisely on the articular edge of the intact supraspinatus tendon and the other arm of the caliper on the lateral bursal-side edge of the insertion. The anterior and posterior insertions of the supraspinatus were exposed in a similar fashion, and the digital caliper was used to measure the length of the insertion. This procedure permitted a contact area to be calculated. Although the supraspinatus footprint does not represent a true rectangle, these measurements provided a consistent means to compare the contact areas of the intact and repaired supraspinatus tendons. The entire supraspinatus tendon insertion was then released sharply from the articular margin laterally, and the distal 10 mm of the supraspinatus tendon was excised to simulate a rotator cuff defect.[3,17] After the supraspinatus tendon insertion was released, the Sharpey fibers outlining the supraspinatus footprint were exposed. To ensure accuracy in measuring, the footprint width and length were measured again.

The specimens were then randomly assigned to 4 different arthroscopic repair techniques, single-row repair or 1 of 3 types of double-row fixation. The double-row methods represented different ways in which the medial anchors were used in the repair: diamond, mattress double anchor (MDA), and modified mattress double anchor (MMDA). These double-row techniques were evaluated because the diamond technique is simply a lateral row of anchors with a medial row of anchors and has been described[12]; the MDA and MMDA configurations are double-row techniques currently used by 2 of the authors and have been reported as arthroscopic techniques.[13]

Each specimen was potted and secured in an upright manner simulating the orientation of the shoulder in a beach-chair position. The shoulders were positioned to enable a "dry" arthroscopic repair technique to be performed.[17] Arthroscopic suture anchors, shuttling devices, and knot tying were used in all repairs, and all repairs were performed with 5-mm bioabsorbable corkscrew anchors (Arthrex Inc, Naples, Fla). Each anchor was loaded with 2 strands of No. 2 FiberWire (Arthrex Inc), and each suture anchor had a suture loop as the anchor eyelet. The nonabsorbable suture was passed in an arthroscopic fashion, using the arthroscopic shuttling devices with various angles of curvature through arthroscopic clear cannulas (Suture Lasso, Arthrex Inc). The number of passes of the suture-shuttling instruments (ie, the number of shuttling maneuvers needed to pass each strand of suture through the tendon to perform the techniques described below) was recorded for each procedure.

Single-Row Repair Technique

The single-row repair was performed using 3 biodegradable corkscrew anchors placed approximately 1 cm lateral to the articular margin in the greater tuberosity. These were placed at the "dead man's angle" to maximize pullout. The first anchor was placed 1 cm lateral to the articular margin adjacent to the midportion of the tear. Second and third anchors were placed 10 mm anterior and posterior to this anchor, respectively. Both strands of No. 2 FiberWire in each anchor were then shuttled in a typical fashion using the Suture Lasso loops. Arthroscopic knot tying was performed using a standard knot pusher with overhand

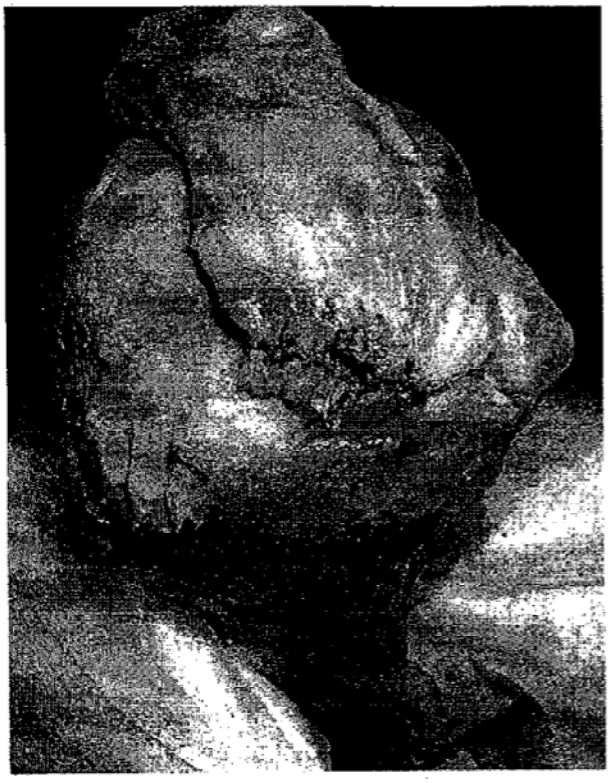


Figure 1. The single-row repair technique.

throws, alternating half-hitches and posts to maximize loop and knot security (Figure 1). These sutures were tied in a simple suture fashion.

Diamond Repair Technique

The diamond repair technique was performed using 2 laterally based 5-mm bioabsorbable corkscrew anchors, each loaded with 2 strands of No. 2 FiberWire. In addition, 1 medial anchor was placed just off the articular margin medial to the lateral 2 anchors. This anchor was also double loaded with No. 2 FiberWire passed using a suturing device as described above; the lateral row of anchors was repaired using the simple suture technique as previously described. The medial anchor sutures were passed in a mattress-type configuration and tied in mattress fashion (Figure 2).

Mattress Double Anchor Repair Technique

For the MDA repair technique (Millett technique[13]), once again the 2 medial anchors were placed just off the articular margin. First, a medial anchor was placed with the eyelet parallel to the articular margin. We used a suture anchor with a loop of suture as the eyelet, so sliding of the suture was easier and abrasion was minimized. Although the anchors used in this study were double loaded, in this technique only 1 suture is used from each medial anchor.

Figure 2. The diamond repair technique.

Using the suture shuttling devices described, each limb of 1 suture from the first medial anchor was shuttled in 2 separate passes 5 mm apart with either a suture hook or a Lasso from the posterior portal or the Neviaser portal.[15] A second anchor was placed laterally approximately 15 mm lateral to the medial anchor. Before placing the lateral anchor, the limbs of suture were reconfigured in the anchor.[13] This step was performed on the back table before insertion. A 5.0 Bio-Corkscrew anchor (Arthrex Inc) was removed from its inserter. Both limbs of the No. 2 FiberWire were removed from the anchor and looped to each other, and the suture limbs were passed back through the eyelet suture loop. All 4 limbs of suture were then passed back through the anchor inserter; the anchor was remounted on the inserter and was prepared for insertion in the greater tuberosity. This anchor was then placed 15 mm lateral to the medial anchor and became the lateral anchor. One limb of suture from the medial anchor was brought to either an anterior or posterior cannula that was empty. Arthroscopically, both limbs of the lead suture of the lateral anchor were brought out of the same cannula in which the single limb of the medial anchor resided. By pulling on these 2 sutures of the lateral anchor, the second suture was brought through the eyelet as a suture loop (Figure 3A). While this was continually brought out of the same cannula in which the single limb from the medial anchor resided, the suture loop was used to transfer the single limb from the medial anchor through the lateral anchor eyelet (Figure 3B). In essence, the sutures in the lateral anchor had been reconfigured to provide a shuttling mechanism to pass a limb of suture from the medial

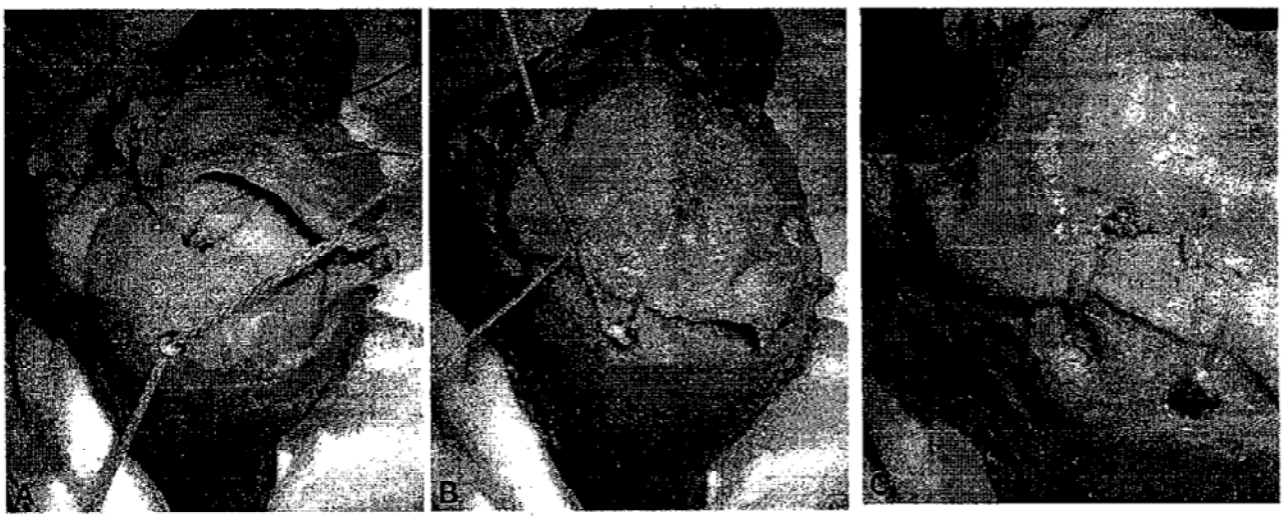


Figure 3. A, medial and lateral anchors are placed for mattress double anchor repair (Millett technique[13]). Note that the lateral anchor sutures have been reconfigured to prepare the shuttling of the medial suture limb through the eyelet of the lateral anchor. B, the medial suture has been shuttled through the eyelet of the lateral anchor. C, the completed mattress double anchor repair.

anchor through the eyelet of the lateral anchor. This configuration was tied with a sliding locking knot of preference. These steps were then repeated with an additional medial anchor and lateral anchor (Figure 3C).

Modified Mattress Double Anchor Repair Technique

For the MMDA repair technique (Guanche or "Viking" technique), the medial anchors were again placed just off the articular margin. The repair was very similar to the method described above, except that both sutures in each medial anchor were used. Using the suture shuttling devices described, 2 limbs of different suture strands were shuttled together through the rotator cuff in 2 separate passes for each medial anchor 5 mm apart. This step was performed with either a suture hook or a Lasso from the posterior portal or the Neviaser portal.[15] The second anchor was placed laterally approximately 15 mm lateral to the medial anchor as mentioned above, with the loops configured in the anchor loop identically to the MDA technique. One limb of suture from the medial anchor was shuttled through the loop in the lateral anchor exactly as described above. This suture was tied establishing a vertical mattress as above. In the MMDA technique, however, the second medial suture was tied in a horizontal mattress medially, providing the arthroscopic equivalent of a modified Mason-Allen suture[9] (Figure 4).

Experimental Testing

At the completion of each repair, the contact area (length and width) of the repaired tendon to the greater tuberosity was measured with a digital caliper for an assessment of the repair footprint and was performed as mentioned previously for the intact tendon. A differential variable reductance transducer (DVRT strain gauge, Microstrain,

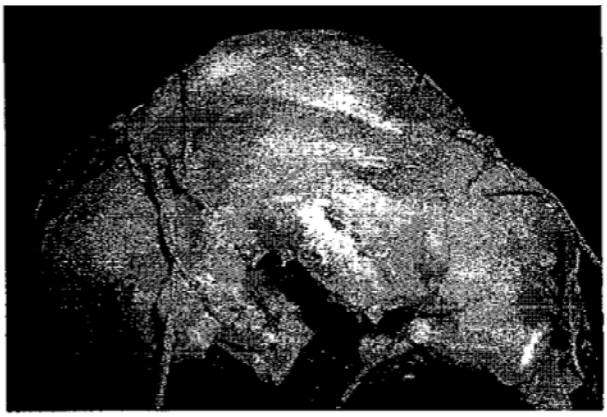


Figure 4. The modified mattress double anchor repair technique (Guanche or "Viking" technique). The lateral anchor sutures are reconfigured as in the mattress double anchor repair, but a medial mattress suture is added.

Burlington, Vt) was then placed bridging the bone and tendon at the repair site to measure displacement (Figure 5).[3] Cyclic loading was performed to 3000 cycles at 1 Hz with an applied 100-N load on a materials testing system (MTS Systems Corp, Eden Prairie, Minn). The 100-N load was chosen for several reasons. The force of the rotator cuff has been estimated to be 9.6 times the weight of the upper extremity.[23] Assuming that an average man weighs approximately 80 kg and that the supraspinatus represents one fourth of the maximum rotator cuff contraction, we deemed a 100-N load to be appropriate. A 180-N load has been used in other studies, based on an estimated two thirds of the load of a maximum contraction of the rotator cuff.[3,20] We chose a lower load because it has been shown that the estimated activity of the supraspinatus during

TABLE 1
General Characteristics[a]

Variable	Single-Row Repair	Double-Row Repair		
		Diamond	MDA	MMDA
Age, y	74 ± 15	70 ± 11	81 ± 11	80 ± 11
Bone mineral density, g/cm^2	0.16 ± 0.11	0.15 ± 0.06	0.16 ± 0.10	0.14 ± 0.04
Intact length, mm	26.26 ± 1.21	26.21 ± 2.19	28.07 ± 2.02	26.26 ± 0.92
Repaired length, mm	25.14 ± 1.04	25.56 ± 2.25	23.92 ± 2.84	21.29 ± 6.94
Intact width, mm	15.39 ± 0.66	15.52 ± 1.51	15.33 ± 3.04	14.98 ± 1.38
Repaired width, mm	8.34 ± 1.81[b]	16.17 ± 1.52	14.79 ± 1.46	15.65 ± 2.25
Intact footprint area, mm^2	404.2 ± 33.90	409.27 ± 70.50	436.14 ± 114.04	392.79 ± 32.6
Repaired footprint area, mm^2	210.48 ± 50.13[b]	415.85 ± 69.21	354.05 ± 56.71	348.28 ± 150.72
Cyclic displacement, mm	2.28 ± 0.26	2.42 ± 0.71	2.35 ± 1.25	1.79 ± 1.11
Load to failure, N	287.2 ± 27.33	305.0 ± 53.21	256.4 ± 27.80	289.4 ± 102.62
No. of passes through the tendon	6	8	4	8
No. of anchors	3	3	4	4

[a]Values are given as means ± SDs. MDA, mattress double anchor technique; MMDA, modified mattress double anchor technique.
[b]Indicates statistical significance.

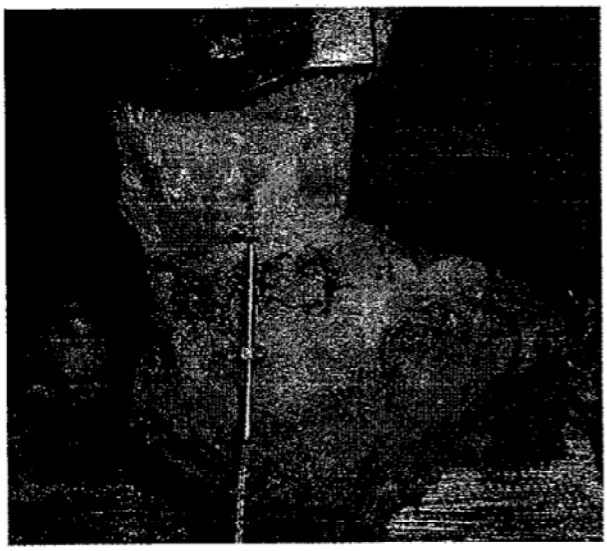


Figure 5. Strain gauge applied for testing displacement.

supine passive forward elevation of the arm is low, and the intention was to evaluate a simulated passive early motion rehabilitation program.

Gap formation greater than 4 mm and load to failure less than 250 N were used as parameters for biomechanical failure.[3,17] There is no known gap size, verified by either in vivo animal studies or human clinical studies, that leads to definite mechanical failure. Previous studies[3,17,20] have used 5 to 10 mm as a parametric range.

Load to failure was determined at a rate of 31 mm/min.[3,17] Based on previous biomechanical work on rotator cuff repair, 250 N was chosen as the minimum ultimate failure load.[3,9,17] This number would represent a load that could be tolerated with early passive motion during rehabilitation after surgery and also a load approaching that achieved with open repairs.[3,9,17]

Statistical Analysis

Power analysis was performed using the parameters of a 4-mm gap and a 250-N ultimate load to failure as significant; it was determined that 20 specimens, with 5 in each treatment group, would be required.

The cyclic displacement, ultimate load to failure, and measurements of the footprint were compared using a 1 × 4 analysis of variance and the Tukey-Kramer post hoc test. Statistical significance was set at $P = .05$, with β error at .80.

RESULTS

There were no statistical differences among the groups for age, sex, or bone mineral density. No differences were found in the measured footprint width, length, and contact area of the intact supraspinatus tendon among the 4 groups, and there were no significant differences in the measured footprint length after repair among the 4 treatment groups. However, the footprint width of the single-row repair technique (8.34 mm) was significantly less than those of the double-row anchor techniques. In fact, all 3 double-row techniques established footprint widths that were statistically equivalent to that of the intact supraspinatus tendon. The mean footprint widths for the double-row techniques were as follows: diamond, 16.17 mm; MDA, 14.79 mm; and MMDA, 15.65 mm. A larger calculated contact area was seen with double-row fixation methods than with the single-row repair technique (see Table 1).

With cyclic loading of 3000 cycles at 100 N, the single-row repair displaced 2.28 mm (range, 1.79-2.50 mm), the diamond technique displacement was 2.42 mm (range, 1.39-3.50 mm), the MDA method displacement was 2.35 mm (range, 1.20-4.60 mm), and displacement for the MMDA technique was 1.79 mm (range, 0.80-3.69 mm). We found no significant differences among the groups with regard to cyclic displacement.

TABLE 2
Modes of Failure[a]

Repair Type	Age, y	Race	Sex	Cause of Death	Mechanism of Failure
Single-row	45	White	Female	Lung cancer	Partial anchor pullout; suture through tendon
Single-row	82	White	Male	ASCVD	Posterior anchor pullout after suture through tendon
Single-row	75	White	Female	COPD	Anchor failure
Single-row	91	White	Male	ASHD	Suture through tendon
Single-row	76	White	Male	MI	Partial anchor pullout; suture through tendon
Diamond	57	White	Male	Liver failure	Tear through tendon proximal to repair
Diamond	57	White	Male	Liver failure	Suture through tendon
Diamond	78	White	Female	CHF	Anchor failure
Diamond	78	White	Male	MI	Suture through tendon and muscle belly
Diamond	81	White	Male	MI	Suture through tendon
MDA	91	White	Female	Lung cancer	Suture through tendon
MDA	67	Black	Female	COPD	Suture through tendon
MDA	96	White	Male	ASHD	Suture through tendon
MDA	72	White	Male	CHF	Suture through tendon
MDA	81	White	Female	MI	Suture through tendon
MMDA	89	White	Female	CVA	Anchor failure
MMDA	91	White	Female	Lung cancer	Suture through tendon
MMDA	81	White	Female	MI	Tendon failure proximal mattress suture
MMDA	78	White	Female	CHF	1 anchor pullout; 1 suture through tendon
MMDA	59	White	Male	MI	Suture through tendon

[a]ASCVD, arterial sclerotic cardiovascular disease; ASHD, arterial sclerotic heart disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; MDA, mattress double anchor technique; MI, myocardial infarction; MMDA, modified mattress double anchor technique.

With load-to-failure testing, single-row repair failed at 287 N (range, 270-341 N), diamond repair failed at 305 N (range, 274-403 N), MDA technique failure was at 256 N (range, 218-291 N), and MMDA failure was at 289 N (range, 135-390 N). Once again, there were no statistically significant differences among the groups.

The mode of failure is depicted in Table 2. Failure consisted predominantly of the suture tearing through the tendon, followed by screw pullout. There were 2 cases in the double-row technique in which a tear in the supraspinatus tendon occurred proximal to the repair site, again with sutures tearing through the tendon. These tears occurred in 2 double-row repairs in which the medial limbs of sutures cut through the tendon.

In summary, all groups demonstrated superior structural properties when compared to previously published reports. There were no differences in cyclic load or load to failure between any of the groups. The double-row anchor repair provided a consistently larger footprint width.

DISCUSSION

Recurrent defects after open rotator cuff repair occur frequently and have been the subject of considerable debate.[7,8,10,16] The effect of such a defect on functional outcome has been controversial, but it has generally been accepted that an intact rotator cuff tendon after surgery has a better outcome.[7,8,10] Such defects could be due to early loss of fixation or to a less-than-desirable biological healing process with weak reparative tissue.

Failure of fixation may be caused by suture breakage, loss of the suture grasp of the tendon, with the suture cutting through the tendon during cyclic loading, or migration of the suture anchor in osteoporotic bone.[4] Gerber et al[9] evaluated several different suture grasping techniques performed in an open technique. This study led to the recommendation of the use of a modified Mason-Allen stitching technique in open repairs.

In contrast, Burkhart et al[3] in a cadaveric study compared transosseous fixation using simple sutures through bone tunnels versus the mattress configuration. Interestingly, simple sutures had a statistically higher ultimate failure load than did the mattress suture construct. It is difficult to compare these 2 studies, as the mechanical testing process was different. Of note, in the study by Gerber et al,[9] 6 simple sutures did approach 300 N of failure. This finding has important implications for arthroscopic techniques in which a simple suture is placed with the use of suture anchors. Current suture anchors used in rotator cuff repair are frequently loaded with 2 strands of nonabsorbable suture. It is technically feasible to perform an arthroscopic single-row repair using 3 double-loaded anchors representing 6 simple sutures.

In an attempt to improve initial fixation in arthroscopic repairs, the Mason-Allen suture type was evaluated after arthroscopic placement.[12] Interestingly, Schneeberger et al[17] reported inferior initial fixation of this type of suture-grasping method placed in an arthroscopic manner. They compared 2 tendon stitches: a mattress stitch and the modified Mason-Allen stitch. Using an arthroscopic approach, they found that the mattress tendon stitch per-

formed at a much higher and statistically significant failure load (230 N) than did the modified Mason-Allen stitch (168 N).[12] These findings led the authors to conclude that lower holding strength with the use of a No. 2 suture material and bone anchors cannot achieve the same initial fixation strength as open repair techniques, which can use stronger suture and an augmented transosseous suture-to-bone fixation. They further suggested that if the rotator cuff is subject to postoperative loading, the open surgical technique may be preferred until stronger fixation methods are developed.[12]

In arthroscopic suture anchor repair of soft tissue to bone, loop security and knot security are fundamental to resisting slippage and gap formation. The greater number of passes and the difficulty in obtaining loop security with a modified Mason-Allen technique arthroscopically may be the reasons for its inferior mechanical performance as reported by Schneeberger et al.[17]

These studies are especially pertinent in light of the recent study evaluating arthroscopic rotator cuff repair by Galatz et al.[5] They evaluated repair integrity after arthroscopic repair of large and massive rotator cuff tears. These repairs were made with a single row of anchors using a simple suture technique. Using ultrasonography, the authors demonstrated that 89% of these repairs had cuff defects. At 2 years postoperatively, there was a decrease in the average American Shoulder and Elbow Society score from more than 90 points to approximately 79.9 points. Furthermore, the authors noticed an associated decrease in function.

Despite this disheartening information, there are a number of recent clinical reports demonstrating excellent clinical and functional results after arthroscopic rotator cuff repair.[‖] Since the reports by Gerber et al[9] and subsequently by Schneeberger et al,[17] a plethora of suture-shuttling devices, stitching instruments, and punches, as well as the introduction of stronger suture materials, have become available. These technical improvements offer the promise of improving initial mechanical fixation strength. Furthermore, a double row of anchors can now be performed arthroscopically, expanding the footprint area for biological healing and the potential for increasing the initial mechanical strength and durability of the repair.[12,13] From a biomechanical perspective, a previous study documented the superiority of a double-row fixation technique; Waltrip et al[20] compared a transosseous rotator cuff suture technique performed in a mattress-type suture configuration, a single row of anchors repair, and a third group that combined the transosseous lateral tendon repair with the medial suture anchor repair or double-row repair. The mean number of cycles to failure for the combined double-row technique was significantly greater than for either the transosseous suture method with a mattress suture versus a single row of anchors with simple suture technique.

It was therefore our purpose to compare the performance of a simulated arthroscopic repair using single-row fixation to 3 reported types of double-row fixation. Our intent was to evaluate the repair techniques using the same state-of-the-art anchors, dual loaded with ultrastrong nonabsorbable suture material. Specifically, it was our purpose to compare the intact rotator cuff footprint to the footprint after a single-row and double-row repair. Improving the footprint available for tendon-bone healing may have important biological and clinical implications. Furthermore, it was our intent to compare the structural properties of load to failure and cyclic displacement of an arthroscopic single-row repair to several double-row repairs recently described. Finally, we wanted to validate the claim that current arthroscopic techniques had the structural performance equivalent to previously reported open techniques, so as to permit earlier range of motion but not at the expense of mechanical integrity. To our knowledge, there are no previous studies using state-of-the-art suture anchors, shuttling devices, and ultrastrong suture material specifically designed for arthroscopic rotator cuff repair and also comparing single-row versus double-row rotator cuff repair with regard to load to failure, cyclic displacement, and restoration of the supraspinatus footprint. These are the major strengths of this particular study.

Our findings indicate a higher load to failure with arthroscopic suture anchors in single-row repair technique than has been previously reported. There were no significant differences in load to failure and cyclic displacement between single-row repair and each of the double-row repair techniques used in this study. Therefore, we did not confirm our hypothesis that a double-row technique would be a superior construct compared to the single-row method. In our study, the single-row repair featured 3 suture anchors double loaded with No. 2 FiberWire suture and tied with a simple stitch (287 N). This load to failure is very consistent and almost identical to the report of Gerber et al[9] in 1994, in which 6 simple sutures had an ultimate tensile strength of 273 N. The suture used in their study was a No. 2 nonabsorbable braided suture. In our study, the No. 2 FiberWire has mechanical properties equivalent to a No. 5 traditional braided suture.

However, it is important to note that in our study all of these specimens were cycled 3000 times before an ultimate load to failure at 31 mm/min was applied. It is conceivable that the ultimate load to failure would have been much higher without stressing the repair more than 3000 cycles. As in the study by Schneeberger et al,[17] we demonstrated that the arthroscopic rotator cuff repair performed with a simple suture technique is comparable to any of the mattress configurations that were used. The MDA and MMDA techniques were attempts to increase the footprint and provide the arthroscopic equivalent of a Mason-Allen tendon stitch. Schneeberger et al[17] theorized that the mattress stitches allowed a certain amount of thread slippage within the tendon, and after the first few cycles, the loads seemed to be equally distributed between the mattress stitches. However, they reasoned that the sutures of the modified Mason-Allen stitch showed no slippage within the tendons. Thus, the 2 stitches were often not equally tightened, resulting in an unequal distribution of loads and therefore a lower failure load. This phenomenon could account for the lack of superiority of the MDA and MMDA

[‖]References 2, 6, 11, 14, 16, 18, 19, 21, 22.

techniques used in our study. Also, as Burkhart et al[2] have described, the extra length of suture may lead to the inability to maximize loop and knot security and thereby to lower failure loads. However, in our study the displacement was the same among the 4 groups and within the parameters for success that we established at the onset of the study.

The advantage of performing a repair using a single row of anchors with strong suture material and simple suture knots is the comparative ease of such a method. However, the double-row repair technique clearly revealed a statistically significant greater footprint area with digital measurement in our study. This method has the theoretical potential of increased surface area for healing, and if the initial fixation strength is adequate, it should provide for a hardier repair, able to withstand greater loading and leading to a more satisfactory long-term outcome. In vivo animal studies and human clinical trials are necessary to test the potential of improved biological healing that may occur with an increased footprint provided with double-row fixation. These in vivo studies are especially important, as double-row repairs would potentially require longer surgical time and more suture anchors and may be more technically difficult.

In summary, an arthroscopic single-row rotator cuff repair using 3 anchors, each anchor loaded with 2 strands of No. 2 strong nonabsorbable suture, has initial fixation and cyclic loading performance approaching previous reports performed with an open repair technique. From a mechanical perspective, a single-row repair using the newest generation of strong suture material and tying simple knots was equivalent in strength to double-row repair using various mattress-type suturing configurations. The potential advantage of an increased surface area equivalent to the intact tendon after a mattress double-row technique is appealing. However, the possible improvements in biological repair, cuff integrity, and clinical outcome were not proven by this current study. An in vivo animal trial and potentially a clinical study are in progress to help answer these questions.

ACKNOWLEDGMENT

The authors thank Arthrex Inc, Naples, Florida, for the generous research grant that enabled this study to be performed.

REFERENCES

1. Apreleva M, Ozbaydar M, Fitzgibbons PG, Warner JJ. Rotator cuff tears: the effect of the reconstruction method on three-dimensional repair site area. *Arthroscopy*. 2002;18:519-526.
2. Burkhart SS, Danaceau SM, Pearce CE Jr. Arthroscopic rotator cuff repair: analysis of results by tear size and by repair technique—margin convergence versus direct tendon-to-bone repair. *Arthroscopy*. 2001;17:905-912.
3. Burkhart SS, Diaz Pagàn JL, Wirth MA, Athanasiou KA. Cyclic loading of anchor-based rotator cuff repairs: confirmation of the tension overload phenomenon and comparison of suture anchor fixation with transosseous fixation. *Arthroscopy*. 1997;13:720-724.
4. Caldwell GL, Warner JP, Miller MD, Boardman D, Towers J, Debski R. Strength of fixation with transosseous sutures in rotator cuff repair. *J Bone Joint Surg Am*. 1997;79:1064-1068.
5. Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. *J Bone Joint Surg Am*. 2004;86:219-224.
6. Gartsman GM, Khan M, Hammerman SM. Arthroscopic repair of full-thickness tears of the rotator cuff. *J Bone Joint Surg Am*. 1998;80:832-840.
7. Gazielly DF, Gleyze P, Montagnon C. Functional and anatomical results after rotator cuff repair. *Clin Orthop Relat Res*. 1994; 304:43-53.
8. Gerber C, Fuchs B, Hodler J. The clinical and structural results of direct repair of massive tears of the rotator cuff. Read at: the Annual Meeting of the American Shoulder and Elbow Surgeons, New Orleans, La. Mar 22, 1998.
9. Gerber C, Schneeberger AG, Beck M, Schlegel U. Mechanical strength of repairs of the rotator cuff. *J Bone Joint Surg Br*. 1994;76:371-380.
10. Harryman DT II, Mack LA, Wang KY, Jackins SE, Richardson ML, Matsen FA III. Repairs of the rotator cuff: correlation of functional results with integrity of the cuff. *J Bone Joint Surg Am*. 1991;73:982-989.
11. Kim SH, Ha KI, Park JH, Kang JS, Oh SK, Oh I. Arthroscopic versus mini-open salvage repair of the rotator cuff tear: outcome analysis at 2 to 6 years' follow-up. *Arthroscopy*. 2003;19:746-754.
12. Lo IKY, Burkhart SS. Double-row arthroscopic rotator cuff repair: re-establishing the footprint of the rotator cuff. *Arthroscopy*. 2003;19:1035-1072.
13. Millett PJ, Mazzocca AD, Guanche CA. Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique. *Arthroscopy*. 2004;20:875-879.
14. Murray TF, Lajtai G, Mileski RM, Snyder SJ. Arthroscopic repair of medium to large full-thickness rotator cuff tears: outcome at 2- to 6-year follow-up. *J Shoulder Elbow Surg*. 2002;11:19-24.
15. Neviaser TJ. Arthroscopy of the shoulder. *Orthop Clin North Am*. 1987;18:361-372.
16. Postel JM, Goutallier D, Lavau L, et al. Anatomical results of rotator cuff repairs: study of 57 cases controlled by arthrography [abstract]. *J Shoulder Elbow Surg*. 1994;3:20.
17. Schneeberger AG, von Roll A, Kalberer F, Jacob HA, Gerber C. Mechanical strength of arthroscopic rotator cuff repair techniques. *J Bone Joint Surg Am*. 2002;84:2152-2160.
18. Severud EL, Ruotolo C, Abbott DD, Nottage WM. All-arthroscopic versus mini-open rotator cuff repair: a long-term retrospective outcome comparison. *Arthroscopy*. 2003;19:234-238.
19. Tauro JC. Arthroscopic rotator cuff repair: analysis of technique and results at 2- and 3-year follow-up. *Arthroscopy*. 1998;14:45-51.
20. Waltrip RL, Zheng N, Dugas JR, Andrews JR. Rotator cuff repair: a biomechanical comparison of three techniques. *Am J Sports Med*. 2003;31:493-497.
21. Wilson F, Hinov V, Adams G. Arthroscopic repair of full-thickness tears of the rotator cuff: 2- to 14-year follow-up. *Arthroscopy*. 2002;18:136-144.
22. Wolf EM, Pennington WT, Agrawal V. Arthroscopic rotator cuff repair: 4- to 10-year results. *Arthroscopy*. 2004;20:5-12.
23. Zuckerman JD, Matsen FA. Biomechanics of the shoulder. In: Nordin M, Frankel VH, eds. *Basic Biomechanics of the Musculoskeletal System*. 2nd ed. Philadelphia, Pa: Lea & Febiger; 1989:225-247.

Docket No.: KFX.003RX Customer No. 20995

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Michael L. Green, et al.
Re-exam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Clark, Jeanne Marie
Art Unit	:	3993
Conf No.	:	1162

STATEMENT OF TATE SCOTT

Commissioner of Patent
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Tate Scott, declare and state that:

1. I am CEO of KFx Medical Corp., the assignee of U.S. Patent No. 7,585,311 upon which the above-identified re-examination is based.

2. An Information Disclosure Statement was filed on January 30, 2007 in the application that issued as U.S. Patent No. 7,585,311. That Information Disclosure Statement included as item #147 an article authored by Peter Millett et al., entitled "Mattress double anchor footprint repair: a novel, arthroscopic rotator cuff repair technique," *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, 20(8):875-879 (2004).

3. An Information Disclosure Statement is being filed herewith in the above-identified re-examination that includes an abstract of which Peter Millett is a co-author (Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown) and another article of which Peter Millett is a co-author (Mazzocca et al., "Arthroscopic Single-Row Versus Double-

Row Suture Anchor Rotator Cuff Repair," *The American Journal of Sports Medicine*, 33:1861 (2005)).

4. I had a conversation with Peter Millett during which he told me that the procedures referenced in the 2004 article had been performed in the two years preceding publication of the article.

5. He also confirmed that all of the procedures were performed by tying knots as described in the 2004 article.

6. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Date: Apr. 12, 2011

w Tate Scott

Tate Scott

KFX.003RX PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Michael L. Green, et al.
Reexam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Jeanne M. Clark
Art Unit	:	3993
Conf. No.	:	1162

CERTIFICATE OF SERVICE

I hereby certify pursuant to 37 C.F.R. § 1.550(f) that a complete copy of the Information Disclosure Statement and Petition Under 37 C.F.R. § 1.182 filed via EFS Web Filing on April 28, 2011 was served by first class mail, on April 28, 2011, the same day as the filing of said documents with the U.S. Patent and Trademark Office, upon the reexamination requestor at the address indicated below:

King & Spalding LLP
1185 Avenue of the Americas
New York, NY 10036

Dated: April 28, 2011

By: Ryan Melnick
Ryan E. Melnick
Registration No. 58,621
Attorney of Record
Customer No. 20,995
(858) 836-9000

11146334
042811